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**REMARKS**

Claims 2-28 and 50-57 and 60 are pending by this amendment, of which claims 21, 22, 27, 28, 50, 51 and 53 have been amended herein, and claims 20 and 49 have been cancelled. Claims 51 and 52 have been indicated as containing allowable subject matter and thus have been rewritten in independent form in a manner suggested in the Office Action.

Favorable reconsideration of the application is requested in view of the amendments and comments herein.

**I. Finality of Office Action Should be Withdrawn**

In view of the new art cited as grounds for rejection, Applicant respectfully requests that the finality of the Office Action be withdrawn. The Office Action states that the prior amendment necessitated the new ground(s) of rejection. However, newly cited U.S. Pat. No. 5,733,267 to Del Toro was cited against claims (claims 50, 55 and 60). Each of claims 50, 55 and 60 were amended in the previous response simply either to correct typographical errors or to rewrite a dependent claim in independent form, none of which constitute an amendment that would make new grounds for rejection necessary. Therefore, since the Examiner has introduced a new ground of rejection (the Del Toro reference) that was neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 I.E. 1.97(c) with the fee set forth in 37 C.F.R. 1.17(p), the Office Action dated April 27, 2004 should not be made final. See MPEP 706.07(a). For these reasons, Applicant respectfully requests that the finality of the Office Action dated April 27, 2004, be withdrawn.

**II. Rejection of Claims 50, 53-57, 60 under 35 U.S.C. §112**

Claims 50, 53-57, 60 stand rejected under 35 U.S.C. §112.

Claim 50 has been amended to correct a typographical errors by deleting a second recitation of a "body portion" and inserting a word "to" in line 13 thereof. Applicant respectfully requests withdrawal of the rejections of claims 50 and 60.

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Claim 53 has also been amended to correct a clerical error by providing correct antecedent basis for "an open end" of the body portion. Withdrawal of this rejection is also respectfully requested.

**III. Rejection of Claims 18, 19, 53, 54 and 56 Under 35 U.S.C. §103(a)**

Claims 18, 19, 53, 54 and 56 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 5,855,601 to Bessler et al. ("Bessler et al."). Withdrawal of this rejection is respectfully requested for at least the following reasons.

Significantly, the Office Action admits that Bessler et al. fails to disclose the use of a pulmonic animal heart valve, as recited in claim 18. Without the benefit of any prior art teaching, the Office Action then goes on to conclude that it would have been obvious matter of design choice to modify the type of valve used in Bessler et al. to a pulmonic valve. Applicant submits that a heart valve prosthesis and implanter combination recited in claim 18, including a pulmonic valve, has structural and functional features (*e.g.*, generally soft and substantially thin cusps), which, for certain applications, has a propensity for improved valve function and longevity, when compared to many other types of valves (*e.g.*, as disclosed in Bessler et al.). These advantages, which the Court of Appeals for the Federal Circuit mandates must be considered, demonstrate non-obviousness of claim 18 over Bessler et al. and the approaches disclosed in the other art of record. *In re Chu*, 34 U.S.P.Q.2d 1089 (Fed Cir 1995). Applicant submits that the absence of any teaching of employing a pulmonic valve in the type of heart valve prosthesis being claim in claim 18 further weighs on the side of non-obviousness, as it demonstrates the failure of those skilled in the art to appreciate the potential benefits of using a pulmonic valve in the combination of claim 18. See, for example, *Arkie Lures Inc. v. Gene Larew Tackle Inc.*, 43 U.S.P.Q.2d 1294, 1297 (Fed. Cir. 1997), where the Court held that when elements have co-existed for many years and never combined weighs on the side of non-obviousness. Similar to the situation in *Arkie Lures*, *supra*, the combination of claim 18 further represents a solution to a problem (an easily implanted, competent heart valve prostheses) for which there is long felt but unmet need. This becomes clearer when the teachings of Bessler et al. are considered as a whole.

The Office Action further asserts that one of ordinary skill in the art "would have expected Applicant's invention to perform equally well with the type of valve chosen as taught

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by Bessler such that it corresponds to the one being replaced or the claimed pulmonic valve in claim(s) 18 because both heart valve prostheses perform the same function..." Applicant respectfully requests that the Examiner identify a legal basis (statute, rule or legal precedent) to support how an expectation of one skilled in the art about the performance of the combination recited in claim 18, if the structure of claim 18 were modified to use a valve taught by Bessler et al., would affect patentability of claim 18. This contention appears to rely explicitly on improper hindsight to support an obviousness conclusion.

Applicant further submits that, in addition to the other reasons stated herein with respect to claims 18 and 53, claim 56 should be allowed. Claim 56 recites a coaxial relationship between the cylindrical member enclosure and body portion, which is not disclosed or suggested in Bessler et al. Significantly, the Office Action is silent with respect to a teaching of such a relationship, thereby failing to present a prima facie case for obviousness. Additionally, claim 56 recites similar relationship to the subject matter indicated as being allowable in claim 51. Reconsideration and allowance of claims 56 and 57 are respectfully requested.

For these reasons, Applicant respectfully requests reconsideration and allowance of claim 18. Applicant also requests allowance of claims 2-17, 19, 53-57, which depend from claim 18.

#### **IV. Rejection of Claim 17 Under 35 U.S.C. §103(a)**

Claim 17 stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 5,549,665 to Vesely et al. ("Vesely et al."). Withdrawal of this rejection is respectfully requested for at least the following reasons.

Claim 17, which depends from claim 18, is allowable for at least the same reasons as claim 18. Claim 17 further recites that an outer sheath of a substantially biocompatible material covers the exposed parts of the support. The Examiner relies on Vesely et al. It is respectfully submitted that covering the artificial heart valve of Bessler et al. with the covering of Vesely et al. appears contrary to the teachings of Bessler et al. For instance, the use of a cloth covering would significantly compromise the ability to collapse the valve into a small cylinder so that it can be implanted by a catheter, as taught by Bessler et al. Reconsideration and allowance of claim 17 are respectfully requested.

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**V. Rejection of Claim 50, 55 and 60 Under 35 U.S.C. §103(a)**

Claims 50, 55 and 60 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bessler et al in view of newly cited U.S. Pat. No. 5,733,267 to Del Toro (Del Toro). Applicant reiterates its requests that the finality of the action be withdrawn in view of the newly cited Del Toro reference. Withdrawal of this rejection is respectfully requested for at least the following additional reasons.

The Office Action relies on Del Toro for a purported teaching of a handle. Contrary to the position in the Office Action, Del Toro, does not teach a handle portion attached to the body portion at a position near a substantially opposite end of the body portion from which the cylindrical member extends, as recited in claim 50. Instead, Del Toro discloses a manifold stabilizer 40 (not a handle) that operates to hold the inner shaft 36 in position during pull back of a middle pull back shaft 34 to further prevent flattening of the outside the body arc or the inside the body arc during deployment (Del Toro at Col. 3, lines 17-29). In view of the failure of Del Toro to provide any teaching or suggestion or motivation to modify the teachings of Bessler et al. (catheter implantation) to include a handle as recited in claim 50, claim 50 is patentable, and its allowance is respectfully requested.

Claims 55 is patentable for at least the same reasons as claim 50, and for at least the reasons that claim 18 is patentable, as described above.

Claim 60 further recites that the valve is a natural tissue pulmonic animal heart valve, and thus is patentable for similar reasons to as described herein with respect to claim 18 and claim 50. Reconsideration and allowance of claim 60 is respectfully requested.

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**VI. Rejection of Claim 20-28, 49 and 57 Under 35 U.S.C. §103(a)**

Claims 20, 21, 28, 49 and 57 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bessler et al. in view of U.S. Pat. No. 5,851,210 to Torossian ("Torossian"). It is submitted that the rejection of claims 20, 21, 28 and 49 are moot in view of the amendments herein. In particular, claims 20 and 49 have been cancelled, and claims 21 and 28 now depend from allowable claim 51. Additionally, claims 22-27 now depend directly or indirectly from claim 51. Allowance of claims 21-28 is respectfully requested.

Claim 57 depends from claim 56, which depends from claim 53, which depends from claim 18. Claim 57 is allowable for at least the reasons as the base and intervening claims as mentioned above.

For the reason described above, claims 21, 28 and 57 are patentable over the cited art, and their allowance is respectfully requested.

**VII. Allowable Subject Matter**

Claims 51 and 52 have been indicated as containing allowable subject matter. Accordingly, Claim 51 has been rewritten in independent form incorporating claims 49 and 20 from which it depended, as suggested in the Office Action. Allowance of claims 51 and 52 is respectfully requested.

**VIII. CONCLUSION**

In view of the foregoing remarks, Applicant respectfully submits that the present application is in condition for allowance. Applicant respectfully requests reconsideration of this application and that the application be passed to issue.

The Examiner is invited to call the undersigned if a telephone interview would be helpful for further prosecution of this matter.

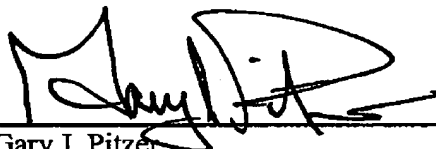
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No fees should be due for the amendments herein as there are the same number independent claims and a reduction in dependent claims. In the event any fees are due in connection with the filing of this document, the Commissioner is authorized to charge those fees to our Deposit Account No. 20-0090.

Respectfully submitted,

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